UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

The Honorable Carlos A. Gimenez
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Gimenez:

Thank you for the letter of February 17, 2021, to the U.S. Environmental Protection Agency (EPA) regarding the Oxitec experimental use permit application for OX5034 *Aedes aegypti* mosquitoes.

Before granting the experimental use permit to Oxitec Ltd. to field test the use of genetically engineered *Aedes aegypti* mosquitoes, EPA conducted an extensive risk assessment based on the best available science and carefully considered public input.[1]

EPA believes Oxitec's field test has the potential to protect public health by reducing mosquito populations. During the field test, Oxitec will release male OX5034 mosquitoes that have been genetically modified to carry a protein. This protein will inhibit the survival of their female offspring when they mate with wild female mosquitoes. The male offspring will survive to become fully functional adults with the same genetic modification, providing multi-generational effectiveness that could ultimately lead to a reduction in *Aedes aegypti* mosquito populations in the release areas. EPA anticipates this may reduce vector pathogens that cause mosquito-borne illnesses like the Zika virus.

Since only adult male OX5034 mosquitoes will be present in the environment and they do not bite people, EPA does not expect the mosquitoes or the trial to present risks to human health. As part of EPA's risk assessment, EPA found that 100 percent of female offspring with the OX5034 trait fail to mature to adulthood, thereby resulting in no female OX5034 mosquitoes released into the environment.[2] Moreover, to ensure that female OX5034 female mosquitoes will not be released or develop in the environment, EPA requires that Oxitec must not release OX5034 mosquitoes within 500 meters of a potential environmental tetracycline source.

In addition, EPA, as a term of issuance and additional safeguard, mandates that Oxitec monitor for OX5034 mosquito offspring. In the unlikely event Oxitec finds genetically modified female offspring, they are required to immediately cease releases, apply conventional pesticides

[1] https://www.regulations.gov/document/EPA-HQ-OPP-2019-0274-0354
[2] https://www.regulations.gov/document/EPA-HQ-OPP-2019-0274-0359

targeting the adult and larval mosquito stages and continue monitoring until no female OX5034 mosquitoes are found for two consecutive generations.

EPA does not expect the trial to have adverse effects to animals in the environment. As part of EPA's risk assessment, EPA determined that the issuance of the experimental use permit would not have an adverse effect on nontarget organisms, including the jeopardization of any threatened or endangered species (i.e., listed species). EPA also concluded the trial would not result in the destruction or adverse modification of the critical habitat of listed species under the Endangered Species Act.

The release of OX5034 mosquitoes is not expected to have any effect on the food chain through ingestion of local popular consumable marine life. As described in EPA's risk assessment, *Aedes aegypti* mosquitoes prefer to lay their eggs in small man-made containers or pools of fresh water. Due to lack of exposure, it is unlikely that the mosquitoes would serve as an integral food source for organisms in marine environments. However, if exposure of marine organisms to OX5034 mosquitoes were to occur, EPA concluded in its risk assessment that there would be no direct or indirect effects to nontarget organisms. This conclusion was based on toxicity studies, bioinformatics analyses and the understanding that proteins in OX5034 mosquitoes are expected to degrade in the environment.

The experimental use permit contains significant protections including weekly monitoring and sampling of the mosquito population in the treatment areas. If an unforeseen event occurs, EPA has maintained the right to cancel the experimental use permit at any point during the 24-month period.

We hope this letter addresses your constituents' concerns. It is the agency's highest priority to ensure that all EPA actions have proper safeguards in place to meet human health and environmental safety standards.

Again, thank you for your letter. If you have further questions, please contact me or your staff may contact Sven-Erik Kaiser in the EPA's Office of Congressional and Intergovernmental Relations at kaiser.sven-erik@epa.gov or at (202) 566-2753.

Sincerely,

Michal Freedhoff, Ph.D.
Acting Assistant Administrator